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| 09/641,540 | 08/18/2000 | Dr. Santosh Misra | 2847-54358 | 6802 |

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EXAMINER

STRZELECKA, TERESA E

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1637

DATE MAILED: 08/06/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/641,540

Applicant(s)

MISRA, DR. SANTOSH

Examiner

Teresa E Strzelecka

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,7-16,19-21,30-37,39-48 and 52-54 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

- 5) ☐ Claim(s) _____ is/are allowed.

- 6) ☒ Claim(s) 1,7-16,19-21,30-37,39-48 and 52-54 is/are rejected.

- 7) ☐ Claim(s) _____ is/are objected to.

- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4. 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I (claims 1, 2, 7-16 and 19-21, drawn to SEQ ID NO: 17) in Paper No. 10 is acknowledged. In paper No. 8, Applicants cancelled claims 2-6 and added new claims 30-37 and 39-54. In paper No. 10, claims 17, 18, 22-29 and 49-51 were cancelled. Therefore, the pending claims under examination are 1, 7-16, 19-21, 30-37, 39-48 and 52-54.

Specification

2. The disclosure is objected to because of the following informalities: Page 32, lines 18 and 19 contains a reference to Figures 20 and 38, which are not in the case.

Appropriate correction is required. No new matter should be introduced.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1, 7-16, 19-21, 30-37, 39-48 and 52-54 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification describes a promoter with SEQ ID NO: 17 (853 base pairs) with a sequence obtained from Douglas fir, and fragments of 187 bp (bases 667-853 of SEQ ID NO: 17), of 456 bp (bases 398-853 of SEQ ID NO: 17) and of 674 bp (bases 180-853 of SEQ ID NO: 17). Constructs comprising these sequences fused to the GUS sequence were

shown to have promoter activity in Douglas-fir seeds only, but not in any other plants (expression of these constructs was tested in tobacco plants, but little or no expression of GUS was obtained, indicating that the promoters did not work). The smallest fragment working as a promoter in Douglas fir cells had 187 bp. Therefore, the Applicant did not show that:

- 1) a nucleic acid sequence with 80% sequence identity to nucleotides 667-853 of SEQ ID NO: 17 functions as a promoter (claim 1),
- 2) 20 consecutive nucleotides of a nucleic acid sequence with 80% sequence identity to nucleotides 667-853 of SEQ ID NO: 17 function as a promoter (claim 36),
- 3) 20 consecutive nucleotides of nucleotides 667-853 of SEQ ID NO: 17 function as a promoter (claim 37),
- 4) a nucleic acid sequence with 90% sequence identity to nucleotides 667-853 of SEQ ID NO: 17 functions as a promoter (claim 34),
- 5) 40 consecutive nucleotides of a nucleic acid sequence with 90% sequence identity to nucleotides 667-853 of SEQ ID NO: 17 function as a promoter (claim 39),
- 6) 40 consecutive nucleotides of nucleotides 667-853 of SEQ ID NO: 17 function as a promoter (claim 40),
- 7) 60 consecutive nucleotides of a nucleic acid sequence with 90% sequence identity to nucleotides 667-853 of SEQ ID NO: 17 function as a promoter (claim 41),
- 8) 60 consecutive nucleotides of nucleotides 667-853 of SEQ ID NO: 17 function as a promoter (claim 42),
- 9) a nucleic acid sequence with 80% sequence identity to nucleotides 398-853 of SEQ ID NO: 17 functions as a promoter (claim 43),

- 10) a nucleic acid sequence with 90% sequence identity to nucleotides 398-853 of SEQ ID NO: 17 functions as a promoter (claim 44),
- 11) a nucleic acid sequence with 80% sequence identity to nucleotides 180-853 of SEQ ID NO: 17 functions as a promoter (claim 46),
- 12) a nucleic acid sequence with 90% sequence identity to nucleotides 398-853 of SEQ ID NO: 17 functions as a promoter (claim 47),
- 13) a nucleic acid sequence with 80% sequence identity to SEQ ID NO: 17 functions as a promoter (claim 52),
- 14) a nucleic acid sequence with 90% sequence identity to SEQ ID NO: 17 functions as a promoter (claim 53),
- 15) SEQ ID NO: 17 and the three tested fragments function as promoters in any plant other than Douglas-fir (claims 14, 16, 30-32),
- 16) SEQ ID NO: 17 and the three tested fragments function as promoters in cells from organisms other than Douglas-fir (claim 15),
- 17) SEQ ID NO: 17 and the three tested fragments function as inducible promoters (induced by ethylene or a metal) (claim 20),
- 18) SEQ ID NO: 17 and the three tested fragments function as promoters in gametophytic tissues (claim 21),

The Applicant did not provide a construct between a promoter of SEQ ID NO: 17 and at least one ORF operably linked to the promoter, a vector or a plant cell comprising the construct (claims 10-12) or construct between a promoter of SEQ ID NO: 17 and cationic peptide (claim 13).

The Applicant describes a modular structure of the promoter of SEQ ID NO: 17, with the smallest fragment functional as a promoter being nucleotides 667-853 of SEQ ID NO: 17, therefore it is not clear which 20, 40 or 60 nucleotides would constitute a functional promoter, or which sequences with 80 or 90% identity to the above sequences would function as a promoter. The promoter modules in a lot of cases require a precise spacing of the modules for functionality, therefore it is critical to determine which nucleotide fragments constitute functional promoter modules (see Vetten et al., Int. J. Biochem., vol. 9, pp. 1055-1068, 1994).

5. Claims 1, 7-16, 19-21, 30-37, 39-48 and 52-54 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a promoter comprising SEQ ID NO: 17 and nucleotides 667-853, 398-853 and 180-853 of SEQ ID NO: 17 and functional in Douglas-fir, does not reasonably provide enablement for sequences with 80 or 90% identity to the above sequences as functional promoters, or for 20 nucleotides of a sequence 80% identical to nucleotides 667-853 of SEQ ID NO: 17 as a functional promoter, or for 40 or 60 nucleotides of a sequence 90% identical to nucleotides 667-853 of SEQ ID NO: 17 as a functional promoter, nor does it provide enablement for a promoter comprising SEQ ID NO: 17 and nucleotides 667-853, 398-853 and 180-853 of SEQ ID NO: 17 being functional in any cells other than Douglas-fir. The specification enables expression of the GUS peptide in Douglas-fir cells, but does not enable expression of any other ORF, including cationic peptides, in these or other cells. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification describes a promoter with SEQ ID NO: 17 (853 base pairs) with a sequence obtained from Douglas fir, and fragments of 187 bp (bases 667-853 of SEQ ID NO: 17), of 456 bp (bases 398-853 of SEQ ID NO: 17) and of 674 bp (bases 180-853 of

SEQ ID NO: 17). Constructs comprising these sequences fused to the GUS sequence were shown to have promoter activity in Douglas-fir seeds only, but not in any other plants (expression of these constructs was tested in tobacco plants, but little or no expression of GUS was obtained, indicating that the promoters did not work). The smallest fragment working as a promoter in Douglas fir cells had 187 bp.

The Applicant describes a modular structure of the promoter of SEQ ID NO: 17, with the smallest fragment functional as a promoter being nucleotides 667-853 of SEQ ID NO: 17, therefore it is not clear which 20, 40 or 60 nucleotides would constitute a functional promoter, or which sequences with 80 or 90% identity to the above sequences would function as a promoter.

Due to the large quantity of experimentation necessary to determine which parts of SEQ ID NO: 17 or its three fragments function as promoters in any host cell, the lack of direction/guidance presented in the specification regarding parts of SEQ ID NO: 17 or its three fragments which may function as promoters in any host cell, the absence of working examples directed to determination which parts of SEQ ID NO: 17 or its three fragments function as promoters in any host cell, the complex nature of the invention, the unpredictability of changes in the promoter sequence on its function due to modular structure of plant promoters (see reference above), undue experimentation would be required of the skilled artisan to make and use claimed invention in its full scope.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1, 7-16, 19-21, 30-37, 39-48 and 52-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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A) Claim 1 is indefinite because of the limitation "... capable of driving the expression of a transgene...". A promoter may not function as a promoter even though theoretically it is capable of doing so, therefore a sequence capable of driving the expression of a transgene is not always a promoter.

8. No references were found teaching or suggesting claims 1, 7-16, 19-21, 30-37, 38-48 and 52-54, but they are rejected for other reasons.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teresa E Strzelecka whose telephone number is (703) 306-5877. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

TS
July 31, 2002 TS


KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER

7/31/02